AMENDMENT UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q92981

U.S. Application No.: 10/567,359

## REMARKS

Claims 52-66 and 68-71 remain in the application, claim 67 having been canceled. Minor editorial amendments have been made to claims 68 and 69. Reconsideration of the application and allowance of all claims are respectfully requested in view of the above amendments and the following remarks.

The objection to claim 68 as a duplicate of claim 67 is believed overcome by the cancellation of claim 67.

All prior art rejections are respectfully traversed. It is respectfully submitted that the invention of Claim 52 is neither shown nor suggested by Wilson, whether Wilson is considered separately or combined with other prior art documents of record.

Claim 52 is directed towards an elongated guide wire for use in a surgical or other procedure for accessing a remote site in the body of a human or animal subject, the guide wire defining:

- (a) a longitudinally extending central axis, and extending between
- (b) a distal end for accessing the remote site and
- (c) a spaced apart proximal end,
- (d) a curvature controllable portion being located in the guide wire towards the distal end thereof for offsetting the distal end at an angle relative to the central axis, the curvature controllable portion comprising
- (e) an elongated curvature inducing first member, and
- an elongated curvature inducing second member
- (g) coupled to each other adjacent their distal ends, and
- (h) extending from their distal ends axially in a proximal direction, and
- being moveable axially relative to each other for inducing a curved bend in the curvature controllable portion, wherein

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 a means is provided for constraining the first and second members to move parallel to each other for inducing the curved bend in the curvature controllable portion.

It is respectfully submitted that the guide wire disclosed by Wilson fails entirely to disclose a guide wire which comprises all of features (a) to (j) of Claim 1. In particular, the guide wire of Wilson fails to disclose feature (d), namely, the provision of a curvature controllable portion being located in the guide wire towards the distal end thereof for offsetting the distal end at an angle relative to the central axis. Indeed, it is respectfully submitted that not only does Wilson fail to disclose such a curvature controllable portion adjacent the distal end of a guide wire, but Wilson fails entirely to disclose any type of curvature controllable portion in his guide wire. Accordingly, by virtue of the fact that Wilson fails to disclose the provision of the curvature controllable portion of feature (d), Wilson automatically fails to disclose any of the remaining features (e) to (j).

It is respectfully submitted that the Examiner has misinterpreted the disclosure of Wilson. Wilson discloses a guide wire which is indicated by the reference numeral 12. The guide wire 12 may be surrounded by a sheath 14. Wilson also discloses a torquer which is indicated by the reference numeral 10 for facilitating rotation of the guide wire about its longitudinally extending central axis. The rotation of the guide wire 12 about its longitudinally extending central axis is also referred to in the specification of Wilson as torquing of the guide wire. The torquer 10 of Wilson is solely provided to clip onto the proximal end of a guide wire, in other words, the part of the guide wire which is not inserted into the subject to provide a handgrip on the guide wire in order to facilitate rotation of the guide wire by a physician. Wilson sets out to address the problems which are encountered by a physician when trying to rotate a guide wire by gripping the proximal end of the guide wire, particularly by a gloved hand. Because of the small diameter of the guide wire, when gripped by a gloved hand, the guide wire would slip in the gloved hand and/or the guide wire would cause "bunching" or "rolling" of the glove, both of which problems result in poor grip and poor control of the guide wire. Accordingly, the torquer 10 provided by Wilson when clipped or secured onto the proximal end of the guide wire provides a handgrip

which permits a physician to gain a sound purchase on the torquer and in turn the guide wire.

Due to the relatively large diameter of the torquer relative to the guide wire, when gripped by a gloved hand, there is no danger of the torquer slipping in the physician's gloved hand or of "bunching" or "rolling" of the glove.

Briefly, the torque 10 of Wilson comprises a body 16 having a longitudinally extending guide wire accommodating first channel 34 for engaging the guide wire 12. A button 20 is located in a cavity 36 formed in the body 16, and is depressible into the cavity 36 against two resilient elastomer blocks 18. The first channel 34 in the body 16 extends into the cavity 36, and a corresponding guide wire accommodating second channel 68 is formed in the button 20, which is alignable with the first channel 34 in the body 16 when the button 20 is depressed downwardly into the cavity 36 against the elastomer blocks 18. The torquer 10 is engaged on the proximal end of the guide wire 12 by firstly depressing the button 20 into the cavity 36 in order to align the second channel 68 in the button 20 with the first channel 34 in the body 16, and the guide wire is then engaged in the respective channels 34 and 68. By releasing the button 20, the elastomer blocks 18 urge the button 20 upwardly within the cavity 36, so that the respective channels 34 and 68 are offset with the guide wire 12 effectively clamped in the channels 34 and 64 by the upward urging action of the elastomer blocks 18 on the button 20.

The torquer 10 of Wilson has no other function than to act as a handle to provide a grip for a gloved hand of a physician to facilitate rotating or torquing of the guide wire in order to facilitate manipulation of the guide wire through a vascular system.

There is no disclosure, nor is there any suggestion in Wilson of the torquer having any function whatsoever in forming or inducing a curved bend in the guide wire 12. The fact that the guide wire 12 of Wilson is illustrated in Fig. 1 of the specification with the proximal portion, which is adjacent the torque 10 effectively doubled back on itself has nothing whatsoever to do with the torquer or its effect on the guide wire. Accordingly, it is respectfully submitted that Wilson fails to disclose the invention of Claim 52.

Furthermore, it is respectfully submitted that nowhere in the disclosure of Wilson is there any suggestion that the guide wire of Wilson could comprise any type of curvature controllable portion, nor is there any suggestion in the disclosure of Wilson of any means for inducing a curved bend in the guide wire of Wilson. Accordingly, it is respectfully submitted that Claim 52 is novel, and furthermore, is not obvious over the disclosure of Wilson.

Additionally, it is respectfully submitted that neither Pacetti in U.S. published Patent Application Specification No. 2003/0120148 nor Gardeski in U.S. Patent Specification No. 7,101,361, which were cited by the Examiner, disclose an elongated guide wire for use in a surgical or other procedure for accessing a remote site in the body of a human or animal subject which includes all the features (a) to (j) of Claim 52.

Pacetti merely discloses a guide wire 10 comprising a core section 12 which terminates in a rounded distal tip 26, and which is coupled to a rounded body 17 by a helically shaped metallic coil 16. A shaping ribbon 23 extends between a tapered portion 25 of the core section 12 and the rounded body 17. The shaping ribbon 23 is secured in the rounded body 17, and is also secured to the tapered portion 25 of the core section 12 by an intermediate mass 24 which also secures the coil 16 to the tapered portion 25 of the core section 12. Such construction of guide wires, and in particular, the distal portion of a guide wire is well known, and has been well known for many years.

Pacetti fails entirely to disclose feature (d), namely, a curvature controllable portion being located in the guide wire towards the distal end thereof for offsetting the distal end at an angle relative to the central axis of curvature. The shaping ribbon 23 is merely provided to facilitate bending of the distal end of the guide wire. Even if the distal portion of Pacetti were considered to be a curvature controllable portion, which the applicant does not concede, Pacetti fails to disclose features (f) to (j) of Claim 52. Furthermore, even if the shaping ribbon 23 were considered to be a curvature inducing member, which the applicant does not concede, Pacetti clearly fails to disclose a second curvature inducing member, and certainly, Pacetti fails to disclose a pair of curvature inducing members coupled to each other adjacent their distal ends, and extending from their distal ends axially in a proximal direction. Furthermore, and most importantly, Pacetti fails to disclose any means being provided for constraining a pair of

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curvature inducing members to move parallel to each other for inducing a curved bend in a curvature controllable portion. Accordingly, Pacetti fails to disclose the invention of Claim 52.

Additionally, there is no suggestion in the disclosure of Pacetti of the provision of such a pair of curvature inducing members, and there is certainly no suggestion in the disclosure of Pacetti of a means for constraining two such curvature inducing members to move parallel to each other for inducing a curved bend in a curvature controllable portion.

Accordingly, it is respectfully submitted that the invention of Claim 52 is novel in light of the disclosure of Pacetti, and furthermore, it is respectfully submitted that the invention of Claim 52 is not obvious whether Wilson and Pacetti are considered separately or combined.

Gardeski in U.S. Patent Specification No. 7,101,361 also fails to disclose or suggest the invention of Claim 52. Gardeski merely discloses a guide wire which comprises an outer tube 110 and a wire 112 extending through a lumen 113 of the outer tube 110. The wire 112 and the outer tube 110 are secured together at their distal ends. A slot 115 is formed in the outer tube 110 so that when the wire 112 is pulled relative to the outer tube 110, the outer tube 110 bends adjacent a slotted portion 111 within which the slot 115 is formed. However, as the outer tube 110 commences to bend, the wire 112 and the outer tube 110 begin to move away from each other adjacent the slot 115, so that the wire 112 essentially becomes a geometric cord which extends across the bend in the outer tube 110. A reinforcing tube 117 is located within the lumen 113 adjacent the slot 115, and is also provided with a slot 125. The reinforcing tube 117 is allegedly provided for minimizing the amount the wire 112 moves away from the outer tube 110 during bending. However, even with the reinforcing tube 117, on bending of the outer tube 110 adjacent the slot 115, the bent portion of the outer tube 110 still moves sidewardly away from both the reinforcing element 112 and the wire 112. Accordingly, even if the slotted portion 111 of the outer tube 110 of the guide wire of Gardeski were to be considered a curvature controllable portion, which the applicant does not concede, Gardeski clearly fails to disclose the provision of a means for constraining a pair of first and second curvature inducing members to move parallel to each other for inducing a curved bend in a curvature controllable portion. The wire 112 of Gardeski is not constrained to move parallel with the outer tube 110 during bending

of the guide wire at the slotted portion 111 since the wire 112 and the slotted portion 111 of the outer tube 110 clearly move sidewardly apart from each other during bending of the outer tube 110 as discussed by Gardeski in his specification at column 11, lines 46 to 51. In fact, a slightly exaggerated view of how Gardeski would perform when the wire 112 is pulled relative to the outer tube 110 is illustrated in Fig. 1 of U.S. Patent Specification No. 5,662,119, which is assigned to Medtronic Inc., the assignee of the U.S. Patent of Gardeski, and which is referenced in the introduction of Gardeski.

Accordingly, Gardeski clearly fails to disclose the invention of Claim 52.

Additionally, there is no suggestion in the disclosure of Gardeski of a guide wire which includes a means for constraining first and second elongated curvature inducing members to move parallel to each other for inducing the curved bend. Furthermore, it is respectfully submitted that none of the other prior art documents disclose or suggest a guide wire which comprises a curvature controllable portion comprising a pair of elongated curvature inducing members and a means being provided for constraining the elongated curvature inducing members to move parallel to each other for inducing the curved bend in the curvature controllable portion. Accordingly, it is respectfully submitted that the invention of Claim 52 is not obvious whether the disclosures of Wilson, Pacetti and Gardeski are considered separately or combined.

Additionally, it is respectfully submitted that it is precisely the provision of feature (j), namely, the provision of a means for constraining first and second elongated curvature inducing members to move parallel to each other for inducing a curved bend in a curvature controllable portion of a guide wire which provides the invention of Claim 52 with its many advantages over prior art guide wires. The advantages of the invention of Claim 52 are set forth in the present specification from page 9, line 27 to page 11, line 18.

Accordingly, it is respectfully submitted that Claim 52 should be allowable, and allowance is respectfully requested. AMENDMENT UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q92981

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Since Claims 53 to 66 are dependent either directly or indirectly on Claim 52, it is respectfully submitted that since Claim 52 should now be allowable, Claims 53 to 66 should likewise be allowable, and allowance is respectfully requested.

Claim 68 is directed towards a combination of a catheter for use in a surgical or other procedure for accessing a remote site in the body of a human or animal subject, and an elongated guide wire. The elongated guide wire of Claim 68 includes features which are identical to features (a) to (j) of Claim 52, and accordingly, it is respectfully submitted that since Claim 52 should now be allowable, Claim 68 should likewise be allowable, and allowance is respectfully requested.

Claim 69 is directed towards a method for forming an elongated guide wire for use in a surgical or other procedure for accessing a remote site in the body of a human or animal subject. The method of Claim 69 includes features which substantially correspond to features (a) to (j) of Claim 52. Accordingly, it is respectfully submitted that similar comments apply to Claim 69 as apply to Claim 52, and thus, Claim 69 should likewise be allowable, and allowance is respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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